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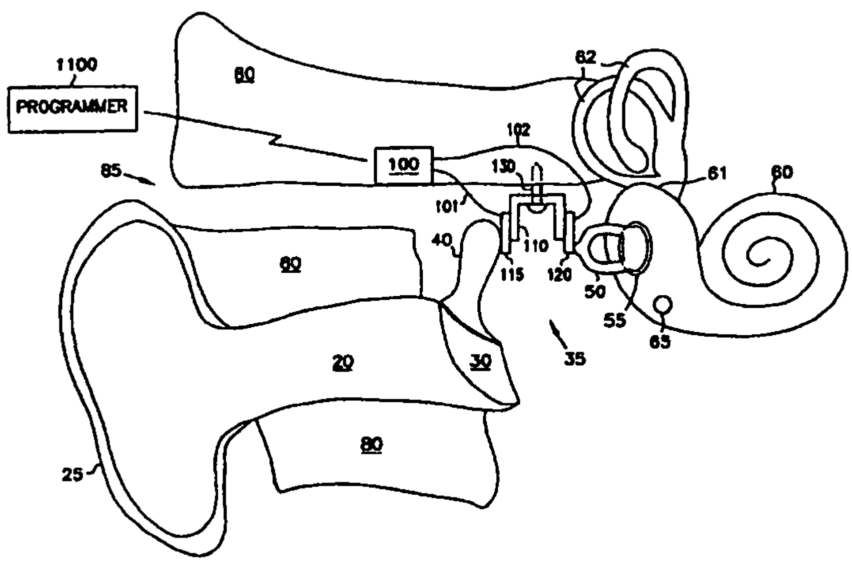

(57) Abstract

A support for input and output transducers of a hearing aid is implanted in the middle ear. The support, which is attached to the mastoid bone, can be a single component or comprise two adjustable components. In one embodiment, an arm extends from the proximal end of the support towards and access hole created behind the outer ear, where the arm is attached for further stability. In another embodiment, the arm extends outside the access hole, where it is mounted subcutaneously to the mastoid bone with a mechanical fastener. The support provides positional adjustability, stability, and is invisible externally. The support can be a single bracket. The transducers are connected to an electronics unit. The electronics can be programmed or reprogrammed.

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HEARING AID TRANSDUCER SUPPORT

Field of the Invention

This invention relates to mounting implantable hearing aid transducers within the middle ear.

Background

In an implantable hearing aid system, transducers within the middle ear engage an auditory element and transduce between electrical signals and mechanical vibrations. Middle ear hearing aid systems are not as susceptible to mechanical feedback as other types of systems. Such systems are more comfortable for the patient than other types of hearing aids, such as those placed directly in the external auditory canal. Transducers which contact an auditory element, such as one of the elements of the ossicular chain, require precise and reliable disposition within the middle ear. This is further complicated by anatomical variations among patients.

Summary of the Invention

An implantable hearing aid (IHA) transducer support is mounted to the mastoid bone within a patient's middle ear region. Input and output transducers are coupled to respective mounting portions on a single support. An electronics unit of the IHA is not attached to the support, simplifying implantation and attachment of the IHA support and transducers. When repairs or adjustments, such as replacing a battery, need to be made to the electronics unit of the IHA, it is not necessary to remove or adjust the support.

In one embodiment, a support comprises a single component. Input and output transducers are coupled to respective mounting portions on opposite ends of the support prior to implantation. In a preferred embodiment, an arm extends from the support towards and into an access hole created behind the outer ear. The access hole is created, extending through the mastoid bone and into the patient's ear. The arm is attached to the mastoid bone at its proximal end, providing more stability to the support. In an even more preferred embodiment,

the arm extends outside the access hole, where it is mounted subcutaneously to the mastoid bone with a bone screw or other mechanical fastener. In a further embodiment, universal connectors are placed between the support and mounting portions for each transducer. The universal connectors, such as ball and socket joints, allow further adjustability and 360 degree movement to position the transducers against respective auditory elements.

In another embodiment, the position of the transducers within the middle ear cavity may be adjusted by manipulating a mechanical fastener that affixes the support to the mastoid bone. In this embodiment, the support comprises two components. Each of the components has an opening. At least one of the openings comprises an adjustment slot. The mechanical fastener extends through mutually-aligned slots/openings on alternate support components within the middle ear region. The distance between the transducers and the angle between the transducers and the support may be independently adjusted by positioning the adjustment slots with respect to the fastener. The resulting IHA support and transducers have positional stability and are invisible externally. In a further embodiment, universal connectors are placed between mounting portions for each transducer and each respective support component. The universal connectors, such as ball and socket joints, allow further adjustability and 360 degree movement to position the transducers against respective auditory elements.

In yet another embodiment, the position of the transducers within the middle ear region may be adjusted by manipulating two mechanical fasteners. In this embodiment, the support also comprises two components. Each component of the support has at least two adjustment slots or openings. Each of the two mechanical fasteners extends through mutually-aligned openings in opposite components. At least one of the two openings, through which a mechanical fastener extends, comprises a slot. The distance between the transducers is adjusted by positioning the adjustment slots/openings with respect to their respective fasteners. The resulting IHA support and transducers also have positional stability and are invisible externally.

In another embodiment of the invention the support includes a single bracket which mounts to a bone in or near the middle ear. One end of a transducer is mounted to single bracket support. The other end of the transducer is postioned on or near a bone in the ossicular chain.

The invention also provides an electronics unit to control the transducer and an external programmer to change the parameters of control for the electronics unit.

Brief Description of the Drawings

Figure 1A is a schematic diagram illustrating a human auditory system in which an access hole is created in the mastoid, to which a single component dual transducer support is affixed.

Figure 1B is a schematic diagram illustrating a further embodiment of the invention shown in Figure 1A, in which ball and socket joints provide further adjustability of transducer position.

Figure 2 is a schematic diagram illustrating a human auditory system, showing an alternate embodiment of the dual transducer support shown in Figure 1A.

Figure 3 is a schematic diagram illustrating a human auditory system, showing an even further embodiment of the dual transducer support shown in Figure 1A.

Figure 4A is a schematic diagram illustrating yet another embodiment of a portion of the dual transducer support shown in Figures 1A, 2, and 3, the support having transducers affixed to opposite sides and having one mechanical fastener with adjustment slots/openings.

Figure 4B is a plan view of the dual transducer support shown in Figure 4A.

Figure 4C is a further embodiment of the invention shown in Figure 4A, in which ball and socket joints provide further adjustability to transducer position.

Figure 5A is a schematic diagram illustrating yet another embodiment of a portion of the dual transducer support shown in Figures 1A, 2, and 3, the support having transducers attached to opposite sides and having two mechanical fasteners with adjustment slots/openings.

Figure 5B is a plan view of the dual transducer support shown in Figure 5A.

Figure 5C is a further embodiment of the invention shown in Figure 5A, in which ball and socket joints provide further adjustability to transducer position.

Figure 6A is a diagram illustrating a single bracket transducer support embodiment having one mechanical fastener with adjustment slots/openings.

Figure 6B is a plan view of the transducer support shown in Figure 6A.

Figure 6C is a further embodiment of the invention shown in Figures 6A and 6B, in which ball and socket joints provide further adjustability for the transducer.

Figure 7 is a schematic diagram illustrating a human auditory system, showing transducer support shown in Figures 6A and 6B.

Detailed Description

The invention provides a transducer support, which is particularly advantageous when used in a middle ear implantable hearing aid system, such as a partial middle ear implantable (P-MEI) or total middle ear implantable (T-MEI) hearing aid system. A P-MEI or T-MEI hearing aid system assists the human auditory system in converting acoustic energy contained within sound waves into electrochemical signals delivered to the brain and interpreted as sound. Figure 1A illustrates generally the use of the invention in a human auditory system. Sound waves are directed into an external auditory canal 20 by an outer ear (pinna) 25. The frequency characteristics of the sound waves are slightly modified by the resonant characteristics of the external auditory canal 20. These sound waves impinge upon the tympanic membrane (eardrum) 30, interposed at the terminus of the external auditory canal, between it and the tympanic cavity (middle ear) 35. Variations in the sound waves produce tympanic vibrations. The mechanical energy of the tympanic vibrations is communicated to the inner ear, comprising cochlea 60, vestibule 61, and semicircular canals 62, by a sequence of articulating bones located in the middle ear 35. This sequence of articulating bones is referred to generally as the ossicular chain. Thus, the tympanic membrane 30 and ossicular chain transform acoustic energy in the external auditory canal 20 to mechanical energy at the cochlea 60.

The ossicular chain includes three primary components: a malleus 40, an incus (not shown), and a stapes 50. The malleus 40 includes manubrium and head portions. The manubrium of the malleus 40 attaches to the tympanic membrane 30. The head of the malleus 40 articulates with one end of the incus. The incus normally couples mechanical energy from the vibrating malleus 40 to the stapes 50. The stapes 50 includes a capitulum portion, comprising a head and a neck, connected to a footplate portion by means of a support crus comprising two crura. The stapes 50 is disposed in and against a membrane-covered opening on the cochlea 60. This membrane-covered opening between the cochlea 60 and middle ear 35 is referred to as the oval window 55. Oval window 55 is

considered part of cochlea 60 in this patent application. The incus articulates the capitulum of the stapes 50 to complete the mechanical transmission path.

Normally, prior to implantation of the invention, tympanic vibrations are mechanically conducted through the malleus 40, incus, and stapes 50, to the oval window 55. Vibrations at the oval window 55 are conducted into the fluid-filled cochlea 60. These mechanical vibrations generate fluidic motion, thereby transmitting hydraulic energy within the cochlea 60. Pressures generated in the cochlea 60 by fluidic motion are accommodated by a second membrane-covered opening on the cochlea 60. This second membrane-covered opening between the cochlea 60 and middle ear 35 is referred to as the round window 65. Round window 65 is considered part of cochlea 60 in this patent application. Receptor cells in the cochlea 60 translate the fluidic motion into neural impulses which are transmitted to the brain and perceived as sound. However, various disorders of the tympanic membrane 30, ossicular chain, and/or cochlea 60 can disrupt or impair normal hearing.

Hearing loss due to damage in the cochlea is referred to as sensorineural hearing loss. Hearing loss due to an inability to conduct mechanical vibrations through the middle ear is referred to as conductive hearing loss. Some patients have an ossicular chain lacking sufficient resiliency to transmit mechanical vibrations between the tympanic membrane 30 and the oval window 55. As a result, fluidic motion in the cochlea 60 is attenuated. Thus, receptor cells in the cochlea 60 do not receive adequate mechanical stimulation. Damaged elements of ossicular chain may also interrupt transmission of mechanical vibrations between the tympanic membrane 30 and the oval window 55.

Various techniques have been developed to remedy hearing loss resulting from conductive or sensorineural hearing disorder. For example, tympanoplasty is used to surgically reconstruct the tympanic membrane 30 and establish ossicular continuity from the tympanic membrane 30 to the oval window 55. Various passive mechanical prostheses and implantation techniques have been developed in connection with reconstructive surgery of the middle ar 35 for patients with damaged ossicles. Two basic forms of prosthesis are available: total

ossicular replacement prostheses (TORP), which is connected between the tympanic membrane 30 and the oval window 55; and partial ossicular replacement prostheses (PORP), which is positioned between the tympanic membrane 30 and the stapes 50.

Various types of hearing aids have been developed to compensate for hearing disorders. A conventional "air conduction" hearing aid is sometimes used to overcome hearing loss due to sensorineural cochlear damage or mild conductive impediments to the ossicular chain. Conventional hearing aids utilize a microphone, which transduces sound into an electrical signal. Amplification circuitry amplifies the electrical signal. A speaker transduces the amplified electrical signal into acoustic energy transmitted to the tympanic membrane 30. However, some of the transmitted acoustic energy is typically detected by the microphone, resulting in a feedback signal which degrades sound quality. Conventional hearing aids also often suffer from a significant amount of signal distortion.

Implantable hearing aid systems have also been developed, utilizing various approaches to compensate for hearing disorders. For example, cochlear implant techniques implement an inner ear hearing aid system. Cochlear implants electrically stimulate auditory nerve fibers within the cochlea 60. A typical cochlear implant system includes an external microphone, an external signal processor, and an external transmitter, as well as an implanted receiver and an implanted single channel or multichannel probe. A single channel probe has one electrode. A multichannel probe has an array of several electrodes. In the more advanced multichannel cochlear implant, a signal processor converts speech signals transduced by the microphone into a series of sequential electrical pulses of different frequency bands within a speech frequency spectrum. Electrical pulses corresponding to low frequency sounds are delivered to electrodes that are more apical in the cochlea 60. Electrical pulses corresponding to high frequency sounds are delivered to electrodes that are more basal in the cochlea 60. The nerve fibers stimulated by the electrodes of the cochlear implant

probe transmit neural impulses to the brain, where these neural impulses are interpreted as sound.

Other inner ear hearing aid systems have been developed to aid patients without an intact tympanic membrane 30, upon which "air conduction" hearing aids depend. For example, temporal bone conduction hearing aid systems produce mechanical vibrations that are coupled to the cochlea 60 via a temporal bone in the skull. In such temporal bone conduction hearing aid systems, a vibrating element can be implemented percutaneously or subcutaneously.

A particularly interesting class of hearing aid systems includes those which are configured for disposition principally within the middle ear 35 space. In middle ear implantable (MEI) hearing aids, an electrical-to-mechanical output transducer couples mechanical vibrations to the ossicular chain, which is optionally interrupted to allow coupling of the mechanical vibrations to the ossicular chain. Both electromagnetic and piezoelectric output transducers have been used to effect the mechanical vibrations upon the ossicular chain.

One example of a partial middle ear implantable (P-MEI) hearing aid system having an electromagnetic output transducer comprises: an external microphone transducing sound into electrical signals; external amplification and modulation circuitry; and an external radio frequency (RF) transmitter for transdermal RF communication of an electrical signal. An implanted receiver detects and rectifies the transmitted signal, driving an implanted coil in constant current mode. A resulting magnetic field from the implanted drive coil vibrates an implanted magnet that is permanently affixed only to the incus. Such electromagnetic output transducers have relatively high power consumption, which limits their usefulness in total middle ear implantable (T-MEI) hearing aid systems.

A piezoelectric output transducer is also capable of effecting mechanical vibrations to the ossicular chain. An example of such a device is disclosed in U.S. Pat. No. 4,729,366, issued to D. W. Schaefer on Mar. 8, 1988. In the '366 patent, a mechanical-to-electrical piezoelectric input transducer is associated with the malleus 40, transducing mechanical energy into an electrical signal,

which is amplified and further processed. A resulting electrical signal is provided to an electrical-to-mechanical piezoelectric output transducer that generates a mechanical vibration coupled to an element of the ossicular chain or to the oval window 55 or round window 65. In the '366 patent, the ossicular chain is interrupted by removal of the incus. Removal of the incus prevents the mechanical vibrations delivered by the piezoelectric output transducer from mechanically feeding back to the piezoelectric input transducer.

Piezoelectric output transducers have several advantages over electromagnetic output transducers. The smaller size or volume of the piezoelectric output transducer advantageously eases implantation into the middle ear 35. The lower power consumption of the piezoelectric output transducer is particularly attractive for T-MEI hearing aid systems, which include a limited longevity implanted battery as a power source.

This invention provides a support 110 for disposing transducers within the middle ear 35 for use in an implantable hearing aid (IHA). The invention is applicable for use with both P-MEI and T-MEI hearing aid systems. The support 110 is capable of carrying both input 115 and output transducers 120 on respective mounting portions. Thus, input 115 and output transducers 120 need not be separately introduced into the middle ear 35. This allows for convenient implantation of both input 115 and output transducers 120 within the middle ear 35. The electronics unit 100 of the IHA is separately implanted. This further eases implantation and repair or adjustment to the electronics unit 100 of the IHA. Maintenance and repairs, such as changing a battery in the electronics unit 100 of the IHA, are easily made without removing the support 110.

For implantation of hearing aid components, an access hole 85 is created in a region of the temporal bone known as the mastoid 80. An incision is made in the skin covering the mastoid 80, and an underlying access hole 85 is created through the mastoid 80 allowing external access to the middle ear 35. The access hole 85 is located approximately posterior and superior to the external auditory canal 20. By placing the access hole 85 in this region, transducers 115 and 120

affixed to a support 110 within the ear cavity 35 can be placed n approximately the same planar level as the auditory elements 40 and 50, which they engage.

In one embodiment, as shown in Fig. 1A, a single component support 110 is implanted into the middle ear cavity 35. Input and output transducers 115 and 120, respectively, are each affixed to the support 110 prior to implantation. One embodiment of the support 110 is illustrated generally in Fig. 1A, comprising one component. However, it is to be understood that the component can be fabricated in multiple parts and coupled together, mechanically or otherwise, to produce a single component support 110. The shape of the support 110 is not critical, provided that the support 110 allows both transducers to be mounted on it, preferably one transducer on each end. However, other configurations are possible, depending on patient anatomy and other factors. The support can be a U-shaped component, as shown in Fig. 1A, or a rectangular shaped component, among other possibilities. One consideration in determining the shape of support 110 is that the spacing between an input transducer 115 and an output transducer 120 disposed on the support 110 is approximately 10 to 20 millimeters, varying depending on the anatomical requirements of the patient.

In this embodiment, at least one input transducer 115 is affixed to a first mounting portion on a proximal end of the support 110. The input transducer 115 mechanically engages at least one auditory element, such as the malleus 40, preferably on the body of the malleus 40 at a force of approximately 10 dynes. At least one output transducer 120 is also affixed to a second mounting portion on a distal end of the support 110. The output transducer 120 is coupled to at least one auditory element, such as the stapes 50, preferably on the head of the stapes 50 at a force of approximately 10 dynes. The transducers 115 and 120 comprise any type of transducer well known to one skilled in the art. In one embodiment, transducers 115 and 120 are ceramic piezoelectric bi-element transducers. Input transducer 115 transduces mechanical energy from vibration of an auditory element, such as the malleus 40, into an electrical signal to the electronics unit 100, which is preferably implanted in the mastoid 80. The electronics unit 100 provides an amplified version of the electrical signal to the

output transducer 120. In response to this amplified electrical signal, the output transducer 120 produces a resulting mechanical vibration, which is coupled to an auditory element such as the stapes 50. The electronics unit 100 is electrically connected to input transducer 115 and output transducer 120 by any convenient technique, indicated schematically as leads 101 and 102, respectively.

The support 110 is also capable of receiving at least one bone screw 130. The bone screw 130 secures the support 110 to the mastoid 80. The bone screw 130 comprises any biocompatible material, and preferably is self-tapping; if so, it is captured by the support 110 and/or an opening created by the bone screw in the mastoid 80, as well known to one skilled in the art. The support 110 also comprises any biocompatible material. Examples of biocompatible materials include titanium, stainless steel, certain ceramics (ex. alumina), certain polymers (ex. polycarbonates), and other materials well known to one skilled in the art. Furthermore, the bone screw 130 can be any type of screw well known to one skilled in the art, such as an orthopedic bone screw, a torx head screw, a single or double slotted head screw. To reduce the number of components handled during implantation of the invention, the support 110 is prefereably adapted to receive and hold the bone screw 130 such that the combination can be placed against the mastoid 80 as a single unit. Any suitable known technique, such as pre-threading or otherwise shaping the support 110 in accordance with known practices, is suitable.

In this embodiment, the incus is removed to prevent feedback of mechanical vibrations from the output transducer 120 to the input transducer 115 through the incus. By affixing the support 110 to mastoid, by a bone screw 130 or other fastener, such as a biocompatible adhesive, mechanical vibrations of the output transducer 120 are not transmitted back to the input transducer 115 through the support 110.

In a further embodiment, as shown in Fig. 1B, universal connectors 190 are placed between mounting portions for each transducer 115, 120 and the main support 110. The universal connectors 190, such as ball and socket joints, allow

further adjustability and 360 degree movement to position the transducers 115 and 120 against respective auditory elements 40 and 50.

In another further embodiment, as shown in Fig. 2, the support 110 further comprises an arm 135, extending from the support 110 towards the outer ear 35 through the access hole 85. A bone screw 145 secures the arm 135 to the mastoid 80 and provides added stability to the support 110. The arm 135 comprises any biocompatible material and is approximately one inch in length, extending approximately to the entrance of the access hole 85 created behind the outer ear 25. The bone screw 145 used to affix the arm 135 to the mastoid 80 is of a similar type as the bone screw 130 used to affix the support 110 to the mastoid 80. The arm 135 also allows for easy insertion of the support 110 into the access hole 85 and the middle ear 35.

In an even further embodiment, as shown in Fig. 3, the support 110 further comprises a lip 150, extending outside the entrance of the access hole 85 from the arm 135, where it is mounted subcutaneously to the mastoid bone 80 with a bone screw 160. The lip 150 extends outward radially from the proximal end of arm 135. The bone screw 160 used to attach the arm 135 to the mastoid bone 80 is of a similar type as the bone screw 130 used to attach the support 110 to the mastoid bone 80. This embodiment increases support 110 stability and eases implantation, due to the addition of the arm 135 and lip 150. However, the arm 135 can be integrally-fabricated with the lip 150, so that they are one piece as in other embodiments.

Figures 1A, 1B, 2, and 3 also include a programmer 1100. The programmer shown includes an external (i.e., not implanted) programmer 1100 communicatively coupled to an external or implantable portion of the hearing assistance device, such as electronics unit 100. Programmer 1100 includes hand-held, desktop, or a combination of hand-held and desktop embodiments, for use by a physician or the patient in which the hearing assistance device is implanted.

In one embodiment, each of programmer 1100 and the hearing assistance device include an inductive element, such as a coil, for inductively-coupled bi-directional transdermal communication between programmer 1100 and the

hearing assistance device. Inductive coupling is just one way to communicatively couple programmer 1100 and the hearing assistance device. Any other suitable technique of communicatively coupling programmer 1100 and the hearing assistance device may also be used including, but not limited to, radio-frequency (RF) coupling, infrared (IR) coupling, ultrasonic coupling, and acoustic coupling.

In one embodiment, the signals are encoded using pulse-code modulation (PCM), such as pulse-width telemetry or pulse-interval telemetry. In pulse-width telemetry, communication is by short bursts of a carrier frequency at fixed intervals, wherein the width of the burst indicates the presence of a "1" or a "0". In pulse-interval telemetry, communication is by short fixed-length bursts of a carrier frequency at variable time intervals, wherein the length of the time interval indicates the presence of a "1" or a "0". The data can also be encoded by any other suitable technique, including but not limited to amplitude modulation (AM), frequency modulation (FM), or other communication technique.

The data stream is formatted to indicate that data is being transmitted, where the data should be stored in memory (in the programmer 1100 or the hearing assistance device), and also includes the transmitted data itself. In one embodiment, for example, the data includes an wake-up identifier (e.g., 8 bits), followed by an address (e.g., 6 bits) indicating where the data should be stored in memory, followed by the data itself.

In one embodiment, such communication includes programming of the hearing assistance device by programmer 1100 for adjusting hearing assistance parameters in the hearing assistance device, and also provides data transmission from the hearing assistance device to programmer 1100, such as for parameter verification or diagnostic purposes. Programmable parameters include, but are not limited to: on/off, standby mode, type of noise filtering for a particular sound environment, frequency response, volume, gain range, maximum power output, delivery of a test stimulus on command, and any other adjustable parameter. In one embodiment, certain ones of the programmable parameters (e.g., on/off,

volume) are programmable by the patient, while others of the programmable parameters (e.g., gain range, filter frequency responses, maximum power output, etc.) are programmable only by the physician.

In another embodiment, the single component support 110, shown in Figures 1 to 3, is replaced with an adjustable support 100, having two components 170 and 165, as shown in Figs. 4A and 4B. In this embodiment, the support 110 allows for independent adjustments of the distance between the input and output transducers 115 and 120, respectively, and the angle between the transducers 115 and 120 with respect to the support mounting screw 130. Such independent adjustments allow multiple auditory elements, such as the malleus 40 and the stapes 50, to be properly coupled to the input and output transducers 115 and 120, respectively, in a patient population having varying anatomical features within the middle ear 35.

The shape of components 165 and 170 in this embodiment is not critical, provided that the support 110 allows both transducers to be mounted on it, preferably one transducer on each end. However, other configurations are possible, depending on patient anatomy and other factors. Components 165 and 170 can be L-shaped, as shown in Fig. 4A, rectangular-shaped, or any other shape that facilitates mounting of transducers 115 and 120. Each support component 165 or 170 can be fabricated as multiple parts coupled together, mechanically or otherwise, to produce a single component 165 or 170.

A mechanical fastener, such as a bone screw 130, couples the support components 165 and 170 together and affixes the support 110 to the mastoid bone 80. However, other types of fastener techniques can be used. For example, one of the two components 165, 170 can be shaped with a flanged arm extending from it, such that the arm extends through the adjustment opening on the opposite component, coupling it with the flange. Each support component 165 and 170 has an opening 175 and 180. At least one of the openings 175, 180 comprises a slot. The bone screw 130 extends through mutually-aligned openings 175 and 180 on alternate support components 165 and 170 within the middle ear region 35. The distance between the transducers 115 and 120 and the

angle between the transducers 115 and 120 with respect to the bone screw 130 are independently adjusted by positioning of the adjustment slots 175 and 180 with respect to the bone screw 130. Adjustment slots 175 and 180 operate by slidable, longitudinal positioning of support components 165 and 170 with respect to each other. The adjustment slots 175 and 180 also operate by radial positioning of each support component 165, 170 with respect to the bone screw 130. The resulting IHA support and transducers have positional stability and are invisible externally. Other types of adjustment techniques can be used in place of adjustment slots 175 and 180.

In a further embodiment, as shown in Fig. 4C, universal connectors 190 are placed between mounting portions for each transducer 115, 120 and the respective main support component 165, 170. The universal connectors 190, such as ball and socket joints, allow further adjustability and 360 degree movement to position the transducers 115 and 120 against respective auditory elements 40 and 50.

In yet another embodiment, the position of the transducers 115 and 120 is adjusted by manipulating two adjustment slots 175 and 180 within the middle ear region 35, as shown in Figs. 5A and 5B. In this embodiment, the support also comprises two components 165 and 170. Again, each support component 165 or 170 can be fabricated in multiple parts and coupled together, mechanically or otherwise, to produce a single component 165 or 170. Each support component 165 and 170 has at least one adjustment slot 175 and 180, respectively. Two mechanical fasteners 130 and 185 extend through both support components 165 and 170 and respective mutually-aligned adjustment slots 175 and 180 on alternate support components 165, 170 within the middle ear region 35. The distance between the transducers 115 and 120 is adjusted by positioning of the adjustment slots 175 and 180. The resulting IHA support and transducers also have positional stability and are invisible externally.

The shape of the two support components 165 and 170 in this embodiment is not critical, provided that the support 110 allows both transducers 115 and 120 to be mounted on it, preferably one transducer 115, 120 on each

end. However, other configurations are possible, depending on patient anatomy and other factors. Each component 165, 170 can be L-shaped, modified L-shaped, as shown in Fig. 5A, rectangular-shaped, or any other shape that facilitates mounting of transducers 115 and 120 to the support 110. A bone screw 130 couples the two components 165 and 170 together and affixes the support 110 to the mastoid bone 80, through an adjustment slot 180 on one component 170. Another screw 185 couples the support components 165 and 170 together through a second adjustment slot 175. This screw 185 comprises a similar material as the bone screw 130 that affixes the support 110 to the mastoid 80, and it can also attach to the mastoid bone 80 for added stability. The distance between the transducers 115 and 120 is adjusted by positioning of the adjustment slots 175 and 180. The adjustment slots 175 and 180 operate by allowing slidable, longitudinal positioning of the two components 165 and 170 with respect to each other. Depending on the fabrication of the components 165 and 170 and their respective adjustment slots 175 and 180, the distance between the transducers 115 and 120 is adjustable by approximately 5 millimeters in either direction. The resulting IHA support and transducers have positional stability and are invisible externally. As with other embodiments, other types of adjustment techniques can be used in place of adjustment slots 175 and 180.

In a further embodiment, as shown in Fig. 5C, universal connectors 190 are placed between mounting portions for each transducer 115, 120 and the respective main support component 165, 170. The universal connectors 190, such as ball and socket joints, allow further adjustability and 360 degree movement to position the transducers 115 and 120 against respective auditory elements 40 and 50.

Figures 6A, 6B, and 6C show a single bracket support 670 having a transducer attached to the single bracket support 670. The single bracket support 670 includes an opening 680. A bone screw 130 passes through the oblong opening 680 and allows for independent adjustment of the distance between the support mounting screw 130, which is typically a bone screw, and the transducer 120. Such adjustment allows flexibility in that the single bracket support can be

mounted with respect to different auditory elements, such as the malleus 40 and the stapes 50, respectively, in a patient population having varying anatomical features within the middle ear 35.

The shape of single bracket support 670 in this embodiment is more or less a flat plate. The transducer 120 is coupled to the flat plate either adhesively, mechanically or otherwise, to produce a single component. It should be noted that other configurations are possible, depending on patient anatomy and other factors. An L-shaped bracket 170, such as is shown in Fig. 4A, a rectangular-shaped bracket, or any other shaped bracket that facilitates mounting of transducer 120 can be used in place of the single bracket support 670. The bone screw 130, couples the single bracket support 670 to the mastoid bone 80. Other types of fastening techniques can also be used. For example, single bracket support 670 can be shaped with a flange that could be attached to the mastoid bone 80. The single bracket support 670 can be moved linearly and rotated with respect to the bone screw 130 to position the transducer 120 in a selected position with respect to one of the elements of the middle ear.

Fig. 6C shows an embodiment having a universal connector 690 placed between the transducer 120 and the single bracket support 670. The universal connector 690 may also be placed between the two portion of the single bracket support 670. The universal connector 690, such as a ball and socket joint, allows further adjustability and 360 degree movement to position the transducer 120 against respective auditory elements 40 and 50.

Fig. 7 is a schematic diagram illustrating a human auditory system, showing transducer support shown in Figures 6A and 6B. In Fig. 7, the bone screw 130 is attached to the mastoid bone 80. The transducer 120 is adjustably in contact with the stapes 40. It should be noted that the transducer 120 could also be adjustably in contact with the malleus 50. Many elements of Fig. 7 are repeated from the previous Figs. 1A, 1B, 2, and 3. For description of these repeated elements please refer to the description related to Figs. 1A, 1B, 2, and 3.

WHAT IS CLAIMED IS:

1. A support for mounting at least two transducers within a middle ear, the support characterizing:

a first mounting portion for disposing within the middle ear a first transducer; and

a second mounting portion for disposing within the middle ear a second transducer.

2. The support of claim 1, in which the support characterizes a single component.

3. The support of claim 1, in which the support characterizes at least two components, adjustably coupled together, and the first and second mounting portions are on first and second components, respectively.

4. The support of claim 1, further characterizing at least one fastener for securing the support to at least one bone in the middle ear.

5. The support of claim 1, further characterizing an arm for adding stability to the support.

6. The support of claim 5, further characterizing at least one fastener for securing the arm to at least a mastoid portion of a temporal bone.

7. The support of claim 5, further characterizing at least one lip extending radially from the arm for adding stability to the support.

8. The support of claim 7, further characterizing a fastener for securing the lip to at least a mastoid portion of a temporal bone.

9. The support of claim 1, further characterizing at least one universal connector adjacent to at least one of the mounting portions, for adjusting the position of the respective transducer with respect to the support.

10. A support combination for mounting at least two transducers within a middle ear, the support characterizing:

a first mounting portion for disposing within the middle ear a first transducer;

a second mounting portion for disposing within the middle ear a second transducer;

a first transducer affixed to the first mounting portion; and

a second transducer affixed to the second mounting portion.

11. The combination of claim 10, in which at least one of the first and second transducers is an input transducer for receiving mechanical vibrations from an auditory element and converting the received mechanical vibrations to electrical signals.

12. The combination of claim 10, in which at least one of the first and second transducers is an output transducer for receiving electrical signals and converting the received electrical signals to mechanical vibrations coupled to an auditory element.

13. The combination of claim 10, further characterizing at least one universal connector adjacent to at least one of the mounting portions, for adjusting the position of the respective transducer with respect to the support.

14. A support system for mounting at least two transducers to at least two auditory elements within a middle ear, the support system characterizing:

a support member;

a first transducer coupled between a first mounting portion of the support member and a first auditory element in the middle ear; and

a second transducer coupled between a second mounting portion of the support member and a second auditory element in the middle ear.

15. The support system of claim 14, in which the support member characterizes a single component.

16. The support system of claim 14, in which the support member characterizes first and second components.

17. The support system of claim 16, in which the first and second components are adjustably coupled to each other with a mechanical fastener.

18. The support system of claim 17, in which the mechanical fastener characterizes a captured, self-tapping bone screw.

19. The support system of claim 17, in which each of the first and second components characterizes at least one slotted opening, and a first slotted opening in the first component is mutually-aligned with at least a portion of a second slotted opening in the second component, and the mechanical fastener extends through the mutually-aligned slotted openings in the first and second components and into a mastoid portion of a temporal bone, such that the first and second components are adjustably coupled to each other.

20. The support system of claim 19, in which the adjustable coupling of the first and second components permits slidable positioning of the first component with respect to the second component.

21. The support system of claim 19, in which the adjustable coupling of the first and second components permits radial positioning of the first component with respect to at least the mechanical fastener.

22. The support system of claim 17, in which the first and second components are adjustably coupled to each other by a pair of slotted openings in each of the first and second components, and a first mechanical fastener extends through the slotted opening in the first component and through the second component, and a second mechanical fastener extends through the slotted opening in the second component and through the first component.

23. The support system of claim 22, in which the adjustable coupling of the first and second components allows for slidable positioning of the first component with respect to the second component.

24. The support system of claim 22, in which at least one of the first and second mechanical fasteners is further coupled to at least a mastoid portion of a temporal bone.

25. The support system of claim 14, in which the support member further characterizes an arm for adding stability to the support.

26. The support system of claim 25, further charcterizing at least one fastener for affixing the arm to at least a mastoid portion of a temporal bone.

27. The support system of claim 25, further characterizing at least one lip extending radially from the arm for adding stability to the support.

28. The support system of claim 27, further characterizing at least one fastener for affixing the lip to at least a mastoid portion of a temporal bone.

29. The support system of claim 14, in which at least one of the first and second transducers is an input transducer for receiving mechanical vibrations from at least one of the auditory elements and converting the received mechanical vibrations to electrical signals.

30. The support system of claim 14, in which at least one of the first and second transducers is an output transducer for receiving electrical signals and converting the received electrical signals to mechanical vibrations coupled to at least one of the auditory elements.

31. The support system of claim 14, further characterizing at least one universal connector adjacent to at least one of the mounting portions, for adjusting the position of the respective transducer with respect to the support.

32. An implantable hearing aid system, the system characterizing:

an electronics unit;

a support member;

a first transducer mounted to a first mounting portion of the support member, coupled to a first auditory element in the middle ear, and electrically-coupled to the electronics unit; and

a second transducer mounted between a second mounting portion of the support member, coupled to a second auditory element in the middle ear, and electrically-coupled to the electronics unit.

33. A method for mounting transducers within a middle ear, the method characterizing:

affixing a support member to a mastoid bone within the middle ear;

mounting a first transducer to a first mounting portion of the support member and coupling the first transducer to a first auditory element in the middle ear; and

mounting a second transducer t a second mounting portion of the support member and coupling the second transducer to a second auditory element in the middle ear.

34. A method for coupling at least two transducers to at least two auditory elements within a middle ear, the method characterizing:

affixing a two-component, adjustably-coupled support member to a mastoid bone within the middle ear;

mounting a first transducer to a first mounting portion of the support member;

mounting a second transducer to a second mounting portion of the support member; and

adjusting the support member to position the first and second transducers against first and second auditory elements.

35. A support for mounting a transducer within a middle ear, the support characterizing:

a bracket adapted for disposing within the middle ear, said bracket having an opening therein;

a transducer coupled to said bracket; and

a bone attachment mechanism associated with the bracket, the position of the transducer with respect to thc bone attachment mechanism being adustable.

36. The support of claim 35 wherein the bone attachment mechanism is a bone screw which passes through the opening in the bracket.

37. The support of claim 35 wherein the bone screw is tightened to fix the adjusted distance between the transducer and the bone screw.

38. The support of claim 35 wherein the bracket further includes a universal joint which can be used to adjust the angle of the transducer.

39. The support of claim 37 wherein the bone screw is tightened to fix the adjusted distance between the transducer and the bone screw.

40. The support of claim 39 wherein a single bracket is used.

41. A implantable hearing system for mounting within a middle ear, the system characterizing:

a bracket adapted for disposing within the middle ear, said bracket having an opening therein;

a transducer coupled to said bracket;

a bonc attachment mechanism associated with the bracket, the position of the transducer with respect to the bone attachment mechanism being adustable; and

an electronics unit electrically coupled to the transducer.

42. The implantable hearing system of claim 41, in which the transducer inputs a signal to the electronics unit.

43. The implantable hearing system of claim 41, in which the electronics unit outputs a signal to the transducer.

44. The implantable hearing system of claim 41 further characterizing a programmer for communicative coupling to the electronics unit.

45. The implantable hearing system of claim 41 wherein the bone attachment mechanism is a bone screw which passes through the opening in the bracket.

46. The implantable hearing system of claim 45 wherein the bone screw is tightened to fix the adjusted distance between the transducer and the bone screw.

47. The implantable hearing system of claim 46 further characterizing a programmer for communicative coupling to the electronics unit.

48. The implantable hearing system of claim 45 wherein the bracket further includes a universal joint which can be used to adjust the angle of the transducer.

49. The implantable hearing system of claim 48 further characterizing a programmer for communicative coupling to the electronics unit.

50. The implantable hearing system of claim 46 wherein the bone screw is tightened to fix the adjusted distance between the transducer and the bone screw.

51. The implantable hearing system of claim 50 wherein a single bracket is used.

52. The implantable hearing system of claim 51 further characterizing a programmer for communicative coupling to the electronics unit.

53. A method for implanting a hearing system within a human, the method characterizing:

mounting a transducer to a single bracket, said bracket for mounting within the middle ear;

adjusting the position of the transducer with respect to an auditory element in the middle ear; and

affixing the single bracket to a mastoid bone within the middle ear.

54. The method of claim 53 further characterizing the steps of:

mounting an electronics unit within a human for electrically communicating with the transducer; and

programming the electronics unit with a programmer.

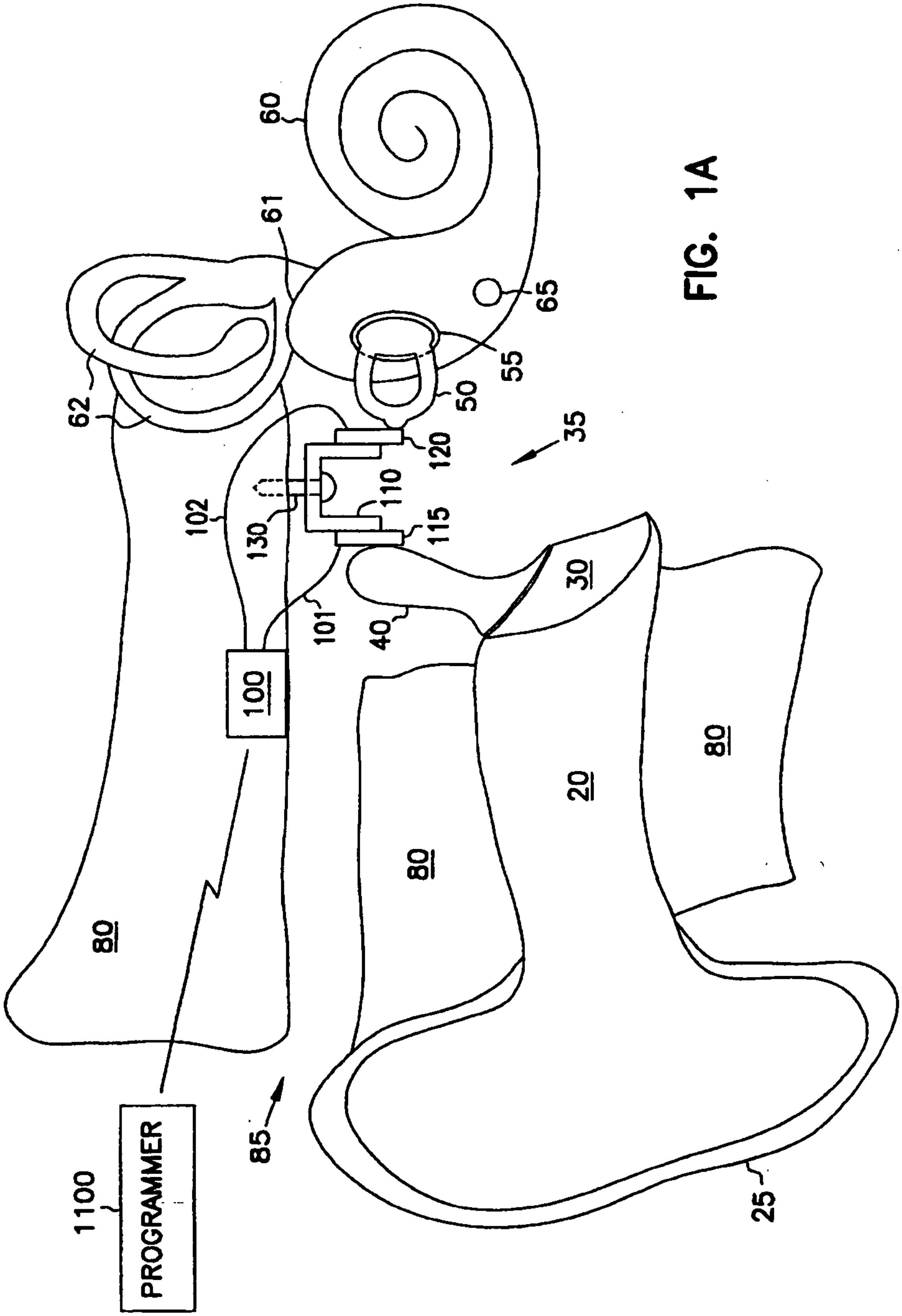
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FIG. 1A

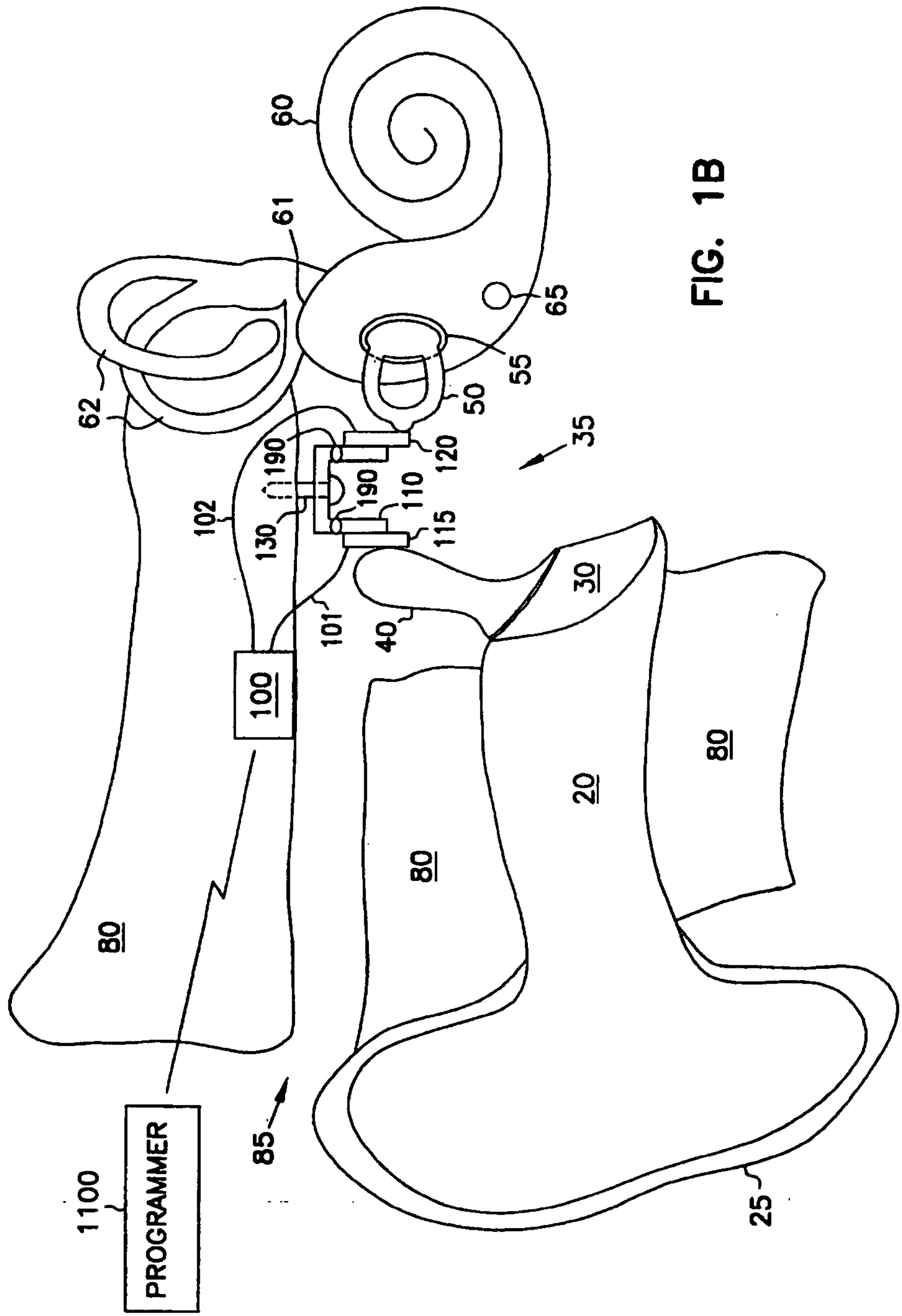
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FIG. 1B

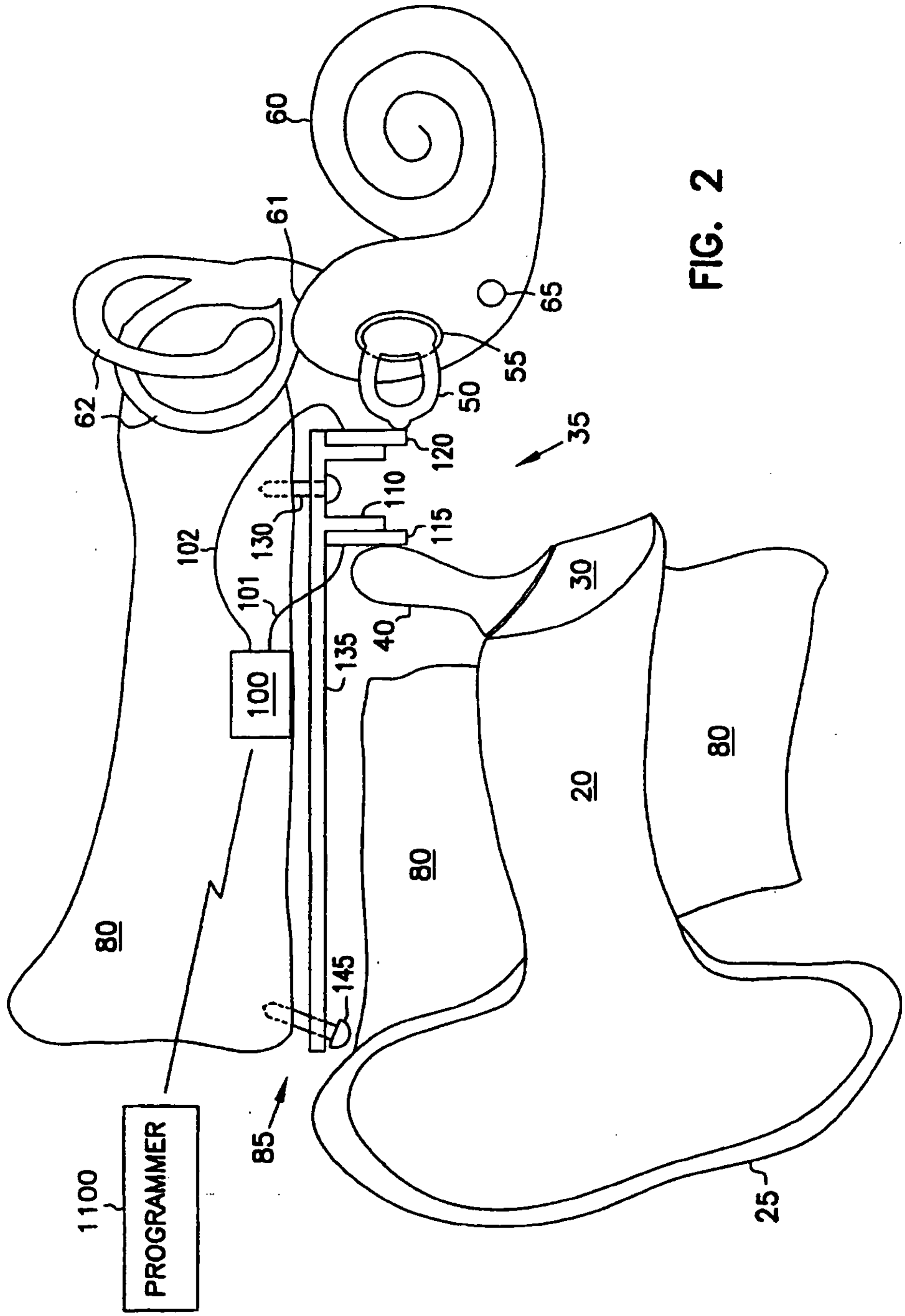
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FIG. 2

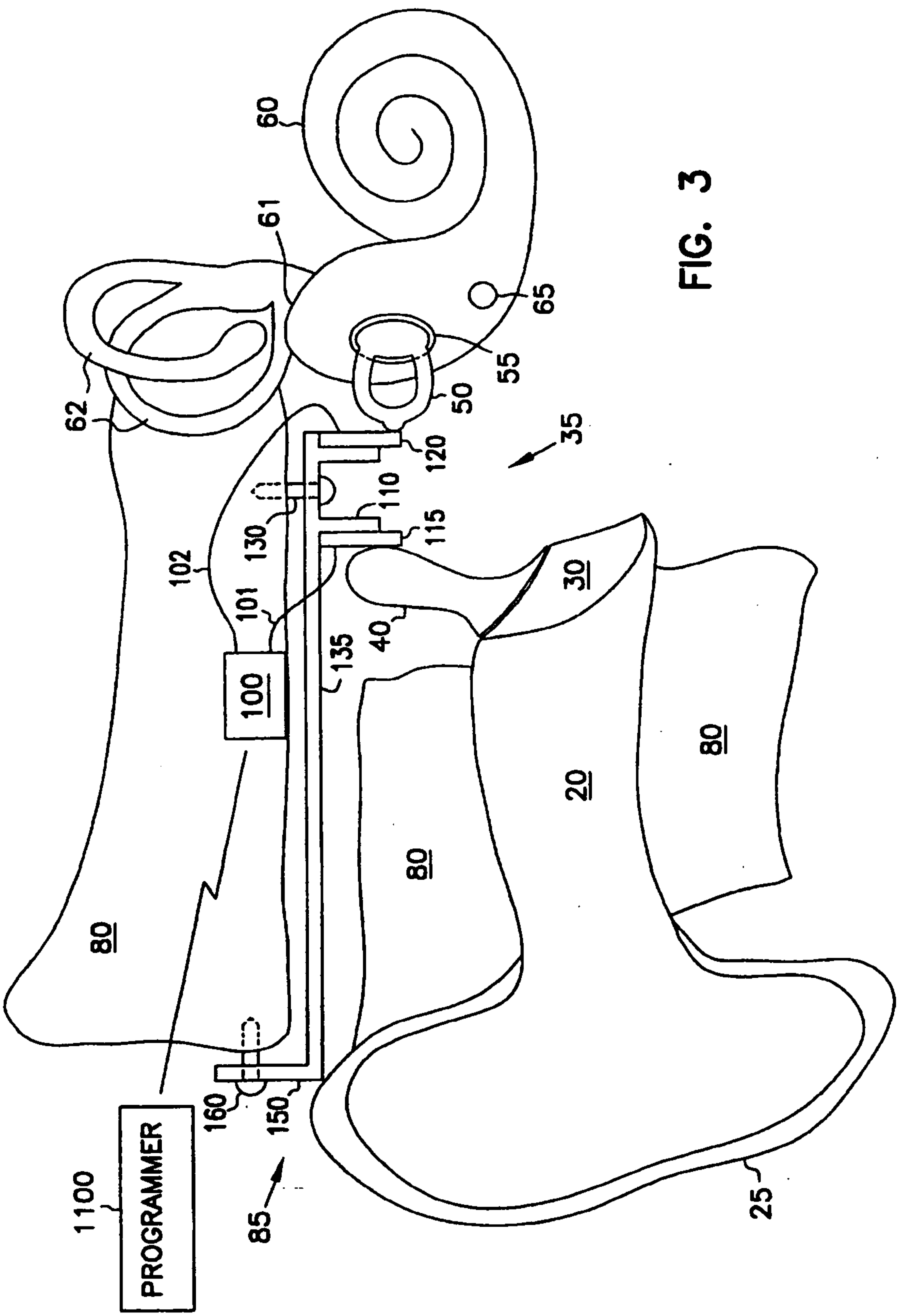
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FIG. 3

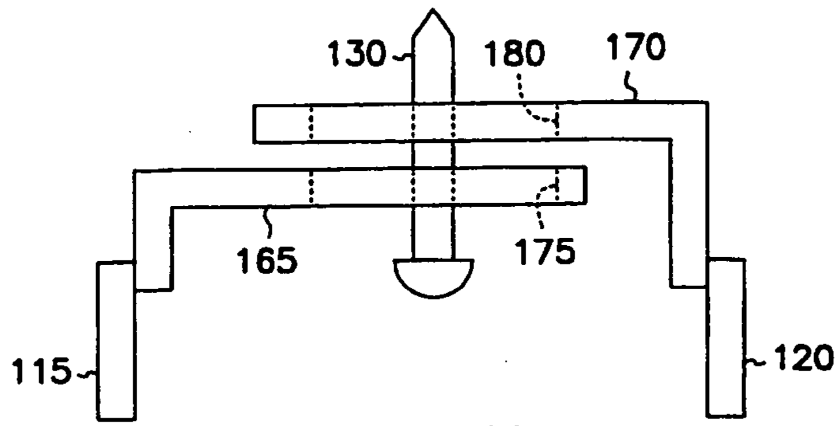

FIG. 4A

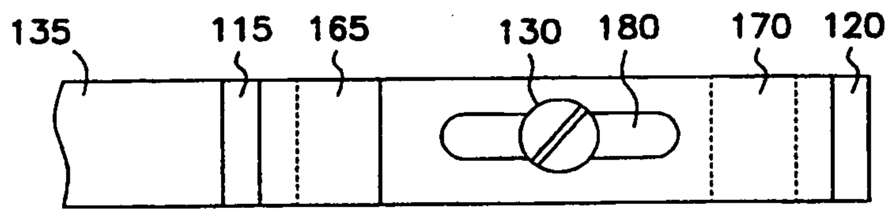

FIG. 4B

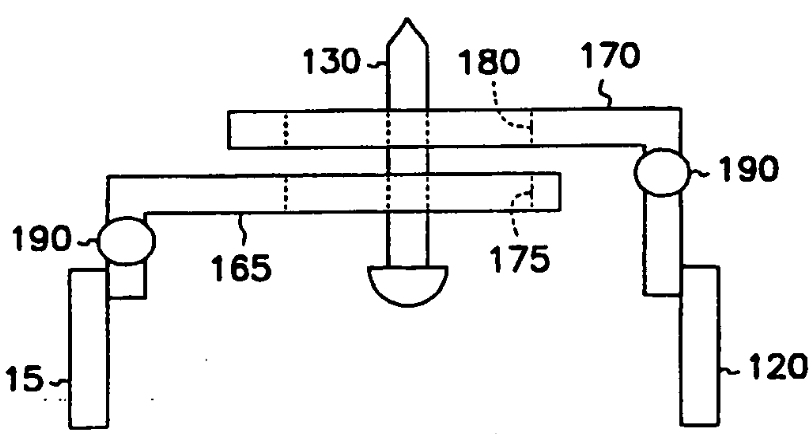

FIG. 4C

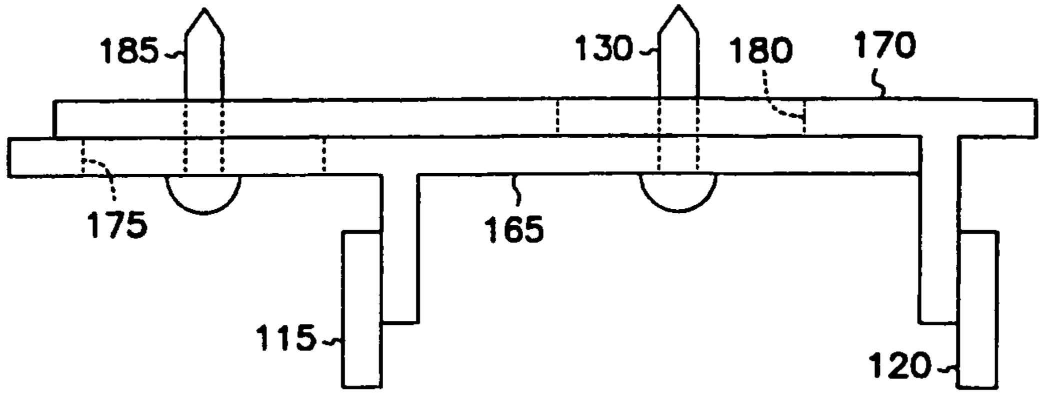

FIG. 5A

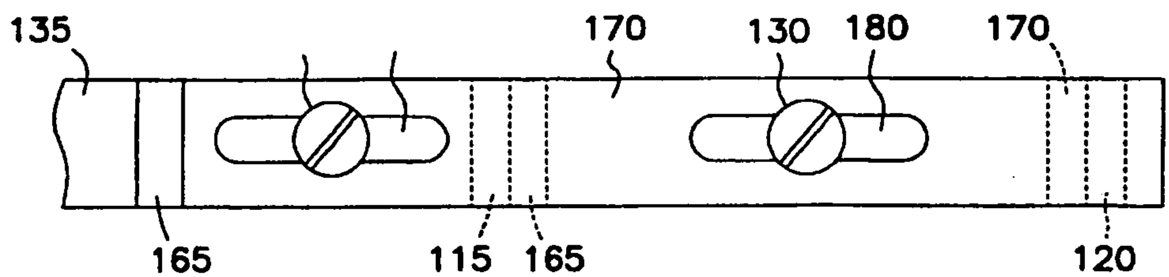

FIG. 5B

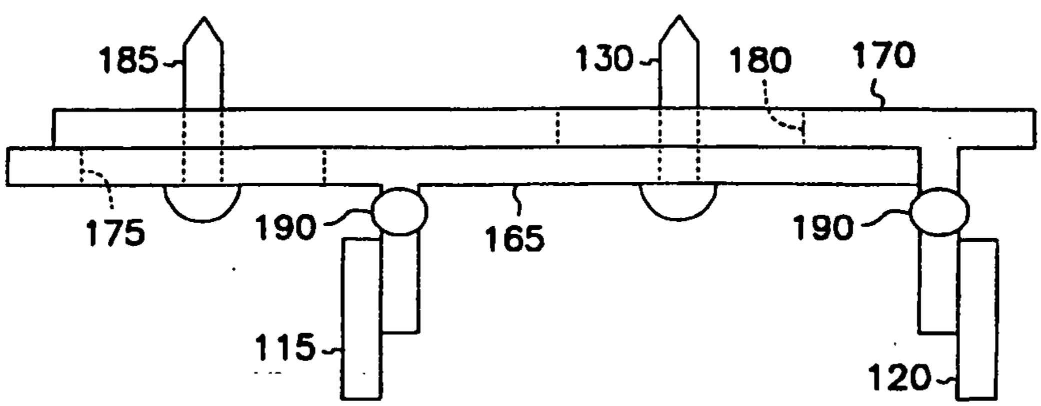

FIG. 5C

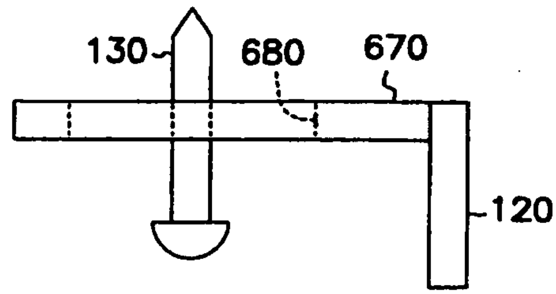

FIG. 6A

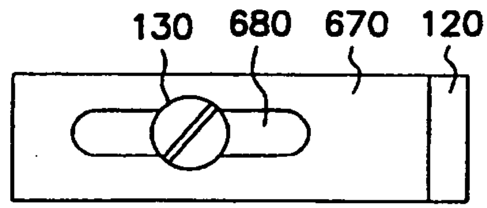

FIG. 6B

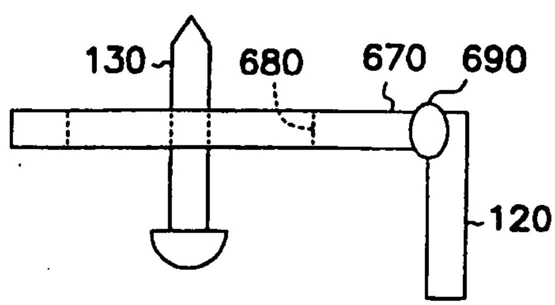

FIG. 6C

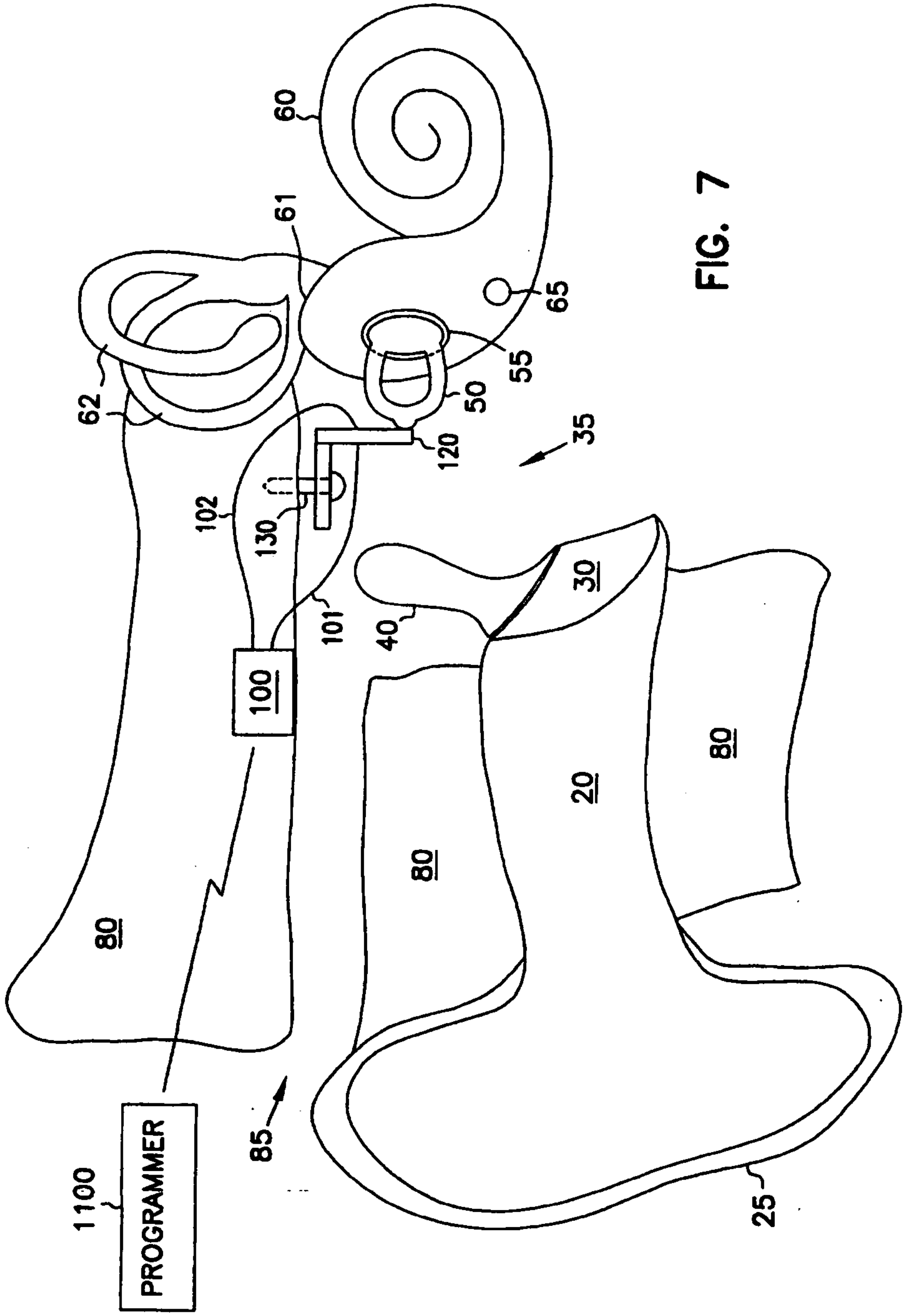
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FIG. 7

INTERNATIONAL SEARCH REPORT

Internat l Application No
PCT/US 97/13808

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 H04R25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 H04R A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 263 254 A (MEDICAL DEVICES GROUP) 13 April 1988	1-6, 9-26, 29-34
A	see column 4, line 33 - column 5, line 35	7,8,27, 28,35, 41-43, 53,54
	see column 6, line 9 - column 11, line 22	

Y	EP 0 520 153 A (AMERICAN CYANAMID COMPANY) 30 December 1992	1-4, 9-24, 29-34
A	see column 2, line 19 - column 3, line 12	35, 41-43, 53,54
	see column 3, line 41 - column 8, line 24	

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

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Date of the actual completion of the international search	Date of mailing of the international search report
30 Oct ber 1997	- 7. 11. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Zanti, P

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	WO 92 08330 A (COCHLEAR PTY. LIMITED) 14 May 1992 see page 1, line 1-5 see page 10, line 14 - page 11, line 24	32, 41-44, 47,49, 52-54

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 97/13808

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